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Suite 700
1455 Pennsylvania Ave., N.W.
Washington, D.C. 20004-1008

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,870,086

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NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,870,086, which claims the human drug product NAROPIN®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,400 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,400 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 18, 1997 (62 Fed. Reg. 38,565). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \tfrac{1}{2}\,(\text{Testing Phase}) + \text{Approval Phase} \\ &= \tfrac{1}{2}\,(2{,}603 - 590) + 544 \\ &= 1{,}551 \text{ days} \end{aligned}$$

Since the regulatory review period began February 14, 1988, before the patent issued (September 26, 1989), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From February 14, 1988 to September 26, 1989 is 590 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 2,603 - 590 = 2013 days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,551 days, would extend the patent from November 24, 2006 (35 U.S.C. § 154) to February 22, 2011, which is beyond the 14-year limit (the approval date is September 24, 1996, thus the 14 year limit is

September 24, 2010). The period of extension is thus limited to September 24, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, November 24, 2006, to and including September 24, 2010, or 1,400 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,870,086
Granted:	September 26, 1989
Original Expiration Date[1]:	November 24, 2006
Applicant:	Rune V. Sandberg
Owner of Record:	Astra Läkemedel Aktiebolag
Title:	Optically Pure Compound and a Process for its Preparation
Classification:	514/330
Product Trade Name:	NAROPIN®
Term Extended:	1,400 days
Expiration Date:	September 24, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: NAROPIN®
FDA Docket No.: 96E-0508